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Attorney Docket No. P19743

In re application of : M. TAKEDA et al.

Serial No. : 09/581,528

Group Art Unit: 1632

Filed : January 07, 1999

Examiner: R. Shukla

For : GENE-MUTATED ANIMAL

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

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Sir:

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Transmitted herewith is an election with traverse in the above-captioned application.

- ___ Small Entity Status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a previously filed statement.
- ___ A verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.
- ___ A Request for Extension of Time.
- ___ No additional fee is required.
- X Supplemental Preliminary Amendment.
- X An Information Disclosure Statement, PTO-1449 Form and References cited.
- The fee has been calculated as shown below:

Claims After Amendment	No. Claims Previously Paid For	Present Extra	Small Entity		Other Than A Small Entity	
			Rate	Fee	Rate	Fee
Total Claims: 50	*50	0	x 9=	\$	x 18=	\$0.00
Indep. Claims: 17	**17	0	x 42=	\$	x 84=	\$0.00
Multiple Dependent Claims Presented			+140=	\$	+280=	\$0.00
Extension Fees for Month				\$		\$0.00
Total:				\$	Total:	\$0.00

*If less than 20, write 20

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___ Please charge my Deposit Account No. 19-0089 in the amount of \$_____.

N/A A Check in the amount of \$_____ to cover the *filing/extension* fee is included.

X The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 19-0089.

X Any additional filing fees required under 37 C.F.R. 1.16.

X Any patent application processing fees under 37 C.F.R. 1.17, including any required extension of time fees in any concurrent or future reply requiring a petition for extension of time for its timely submission (37 CFR 1.136) (a)(3)

Bruce H. Bernstein
Reg. No. 29.027

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Masatoshi TAKEDA et al.

Art Unit: 1632

Serial No : 09/581,528

(National Stage of PCT/JP99/00015)

Examiner: R. Shukla

I.A. Filed : January 7, 1999

For : GENE-MUTATED ANIMAL

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AUG 26 2002

ELECTION WITH TRAVERSE

TECH CENTER 1600 2900

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

This paper is responsive to the Requirement for Restriction mailed from the U.S. Patent and Trademark Office July 22, 2002, in the above application and setting a one-month period for response thereto which runs through August 22, 2002. Inasmuch as this response is being filed within the one-month period for response, it is believed that no extension of time is required. However, if an extension of time is deemed by the Patent and Trademark Office to be necessary, the same is hereby requested and the Patent and Trademark Office is authorized to charge any extension of time fees and any other fees necessary for maintaining the pendency of this application to deposit account No. 19-0089.

Summary of Restriction Requirement

The Restriction Requirement states that the Examiner has determined that the application contains the following distinct inventions or group of inventions, namely:

Group I. Claims 1, 2, 5-9, 12-17, 33, 36-42, drawn to a non-human gene-mutated animal with a mutant presenilin-1 gene;

Group II. Claims 3 and 4, drawn to a non-human gene-mutated animal with a mutant presenilin-1 gene, wherein a particular amino acid has been substituted with another amino acid in the presenilin-1 gene;

Group III. Claim 10, drawn to a non-human gene-mutated animal with a mutant presenilin-2 gene, wherein an amino acid at position 141 and/or 436 is substituted;

Group IV. Claim 11, drawn to a non-human gene-mutated with a mutant presenilin-2 gene, wherein an amino acid at position N141I and/or M239V is substituted;

Group V. Claim 18, drawn to a non-human gene-mutated animal with a mutant presenilin-1 gene and a marker protein;

Group VI. Claims 19, 20, 25, and 26, drawn to a plasmid comprising a DNA of a mutant presenilin-1 gene;

Group VII. Claim 21, drawn to a chromosomal DNA containing exon 8 of a mutant presenilin-1 gene;

Group VIII. Claims 22-23, drawn to a plasmid comprising a chromosomal DNA or cDNA encoding mutant presenilin-1 gene and Sau 3AI site;

Group IX. Claim 24, drawn to a plasmid comprising a certain DNA;

Group X. Claims 27-28, drawn to a plasmid comprising presenilin-1 encoding sequences, a neomycin expression unit flanked by loxPs;

Group XI. Claims 29, 31, and 32, drawn to an embryo comprising a plasmid comprising a certain DNA;

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Group XII. Claim 30, drawn to an embryo comprising a particular plasmid;

Group XIII. Claims 34 and 35, drawn to a method for producing a non-human gene-mutated animal;

Group XIV. Claim 43, drawn to a method of diagnosing Alzheimer's disease or a possibility of onset of Alzheimer's disease using a mutant presenilin-1 gene;

Group XV. Claims 44 and 45, drawn to a substance for treating Alzheimer's disease; and

Group XVI. Claims 46-50, drawn to a hybrid gene mutant animal comprising a mutant presenilin-1 gene and mutant beta amyloid precursor protein.

The Examiner has therefore required that an election be made between these inventions.

Election

In response to the Restriction Requirement, Applicants elect the invention of Group I (claims 1-2, 5-9, 12-17, 33 and 36-42), with traverse.

Traverse

Applicant submits that a restriction is inappropriate in this case and should be withdrawn.

Initially, it should be pointed out that the requirement for restriction omits one of the two criteria of a proper requirement as now established by U.S. Patent and Trademark Office policy that "an appropriate explanation" must be advanced by the Examiner as to the existence of a "serious burden" if a restriction were not required. M.P.E.P. § 803. The requirement for restriction fails to set forth a *prima facie* case for a serious burden. *See id.*

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The requirement for restriction does not give the reasons and/or examples to support the assertion that the examination of the application as filed would result in a serious burden on the Examiner, nor does it set forth an explanation of the separate classification, or separate status in the art, or a different field of search. Due to this omission, it is respectfully submitted that the requirement for restriction is improper and, consequently, its withdrawal is respectfully requested.

The restriction should also be withdrawn because there is no serious search burden. In M.P.E.P. Chapter 800, the Office sets forth its policy by which Examiners are guided in requiring restriction under 35 U.S.C. §121. Section 803 states that “[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.” M.P.E.P. § 803 [R-2], page 800-3 (Rev. 2, July 1996).

In particular, the restriction between Groups I and II should be withdrawn. Although Group I and II differ in that Group I is directed to a non-human gene-mutated animal having a mutant presenilin-1 gene and Group II is directed to non-human gene-mutated animals having a mutant presenilin-1 gene having one or more particular amino acids mutated. A search for non-human gene-mutated having a mutant presenilin-1 gene (Group I) covers non-human gene-mutated having a mutant presenilin-1 gene having one or more particular amino

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acids mutated (Group II). Therefore, as a practical matter, the searches for the four groups appear to be co-extensive. Thus, the search burden would not appear to be serious.

Further, Groups VI and VIII-X differ in that Group VI is directed to a plasmid containing a mutant presenilin-1 gene and Groups VIII-X are directed to specific plasmids containing a mutant presenilin-1 gene. A search for a plasmid containing a mutant presenilin-1 gene (Group VI) covers specific plasmids containing a mutant presenilin-1 gene (Group VIII-X). Thus, the search burden would not appear to be serious.

Groups XI-XIII differ in that Group XIII is directed to a method of using a plasmid containing a mutant presenilin gene to create a non-human gene mutated animal and Groups XI-XII are directed to embryo's which contain a plasmid containing a mutant presenilin gene. A search for a method of using a plasmid containing a mutant presenilin gene to create a non-human gene mutated animal covers non-human animal embryos containing a plasmid with a plasmid containing a mutant presenilin gene. Thus, the search burden would not appear to be serious.

Furthermore, M.P.E.P. §1850 provides that when the PTO considers international applications during the national stage under 35 U.S.C. §371, PCT Rules 13.1 and 13.2 will be followed when considering the unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. §111. According to PCT Rule 13.2, unity of invention exists when there is a technical relationship among the claimed inventions involving one or more technical features. Specifically, M.P.E.P. §1850 states that PCT Rule 13 shall

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be construed as permitting inclusion in the same application of "an independent claim for a given product" with "an independent claim for a use of the said product . . . "

In the present case, the claims of Groups I-II involve claims to non-human animals with various mutant presenilin genes and are not mutually exclusive. Moreover, Group II acts to further define certain mutations of the presenilin-1 gene of Group I. Furthermore, Groups VI and VIII-X claim various plasmids containing mutant presenilin DNA. These plasmids are used to create embryos of the non-human animals with various mutant presenilin genes, as claimed in Groups XI-XIII. Thus, these Groups have a technical relationship as required by PCT Rule 13.2, and the restriction as applied to these Groups (I-II, VI, VIII-XIII) should be withdrawn.

Even under the lower standard for restricting cases filed under 35 U.S.C. §111, restriction of the claims in the present case is inappropriate. Even if the Examiner believes that unity of invention is lacking, the restriction should be withdrawn because, as the Examiner appreciates, in order to justify a requirement for restriction, the difference between the invention defined by the various groups of the claims must be material. Despite this requirement, the Examiner has not stated or offered a definition of what is "materially different" to justify a requirement for restriction, or offered an explanation as to why the mentioned differences are material for restriction requirement purposes.

Absent a definition or explanation of this concept, it is respectfully submitted that the Examiner has not explained how such a difference is "materially different" so as to justify restriction between the Groups. In this regard, the Examiner has merely stated that the two

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Groups are materially different, and thereby concluded that the inventions are distinct. However, the Examiner does not indicate how the difference between the two groups is a material difference to support a requirement for restriction, especially when the search areas for the two groups of invention would significantly overlap.

It is also important for the Examiner to understand that Applicant has paid a filing fee for an examination of all the claims in this application. It is respectfully submitted that such an examination in full is part of the *quid pro quo* for which Applicants have the paid the fees for all of the claims under examination. If, however, the Examiner refuses to examine all the claims paid for when filing this application and persists in requiring Applicant to file a divisional application to allow prosecution of both groups of claims, the Examiner is essentially forcing Applicant to pay duplicative fees for the non-elected or withdrawn claims.

In view of the foregoing, Applicant respectfully requests that the restriction requirement be reconsidered and withdrawn, in view of the lack of a serious burden and the lack of material differences for examination purposes between the Groups.

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If there are any comments or questions, the undersigned may be contacted at the below-listed telephone number.

Respectfully Submitted,
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August 20, 2002
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